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(54) **MEDICAL DEVICE COATING BY LASER CLADDING**

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(57) **ABSTRACT**

Methods for making medical devices having porous coatings. Methods may comprise providing a tubing section having inner and outer surfaces and positioning a nozzle proximate to a target surface of the parent tubing section. A powder form of the porous coating may be delivered toward the tubing section, and a laser may be directed at the powder to melt the powder to form a melt pool. The melt pool can solidify to form the porous coating on the target surface. Portions of the parent tubing section may then be cut away to form the support structure of the medical device, such as a stent.

24 Claims, 6 Drawing Sheets

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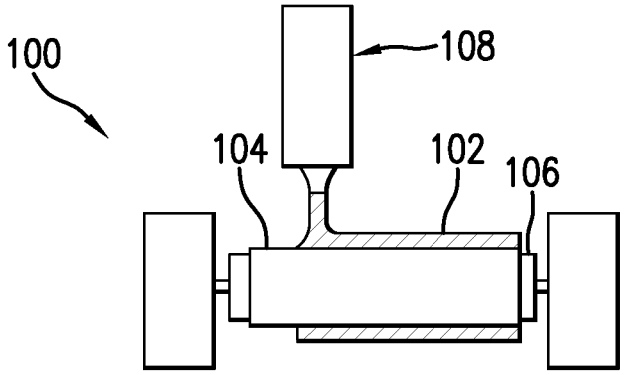

FIG. 1A

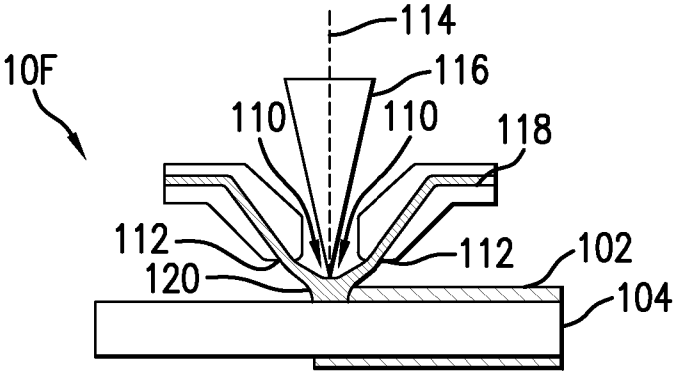

FIG. 1B

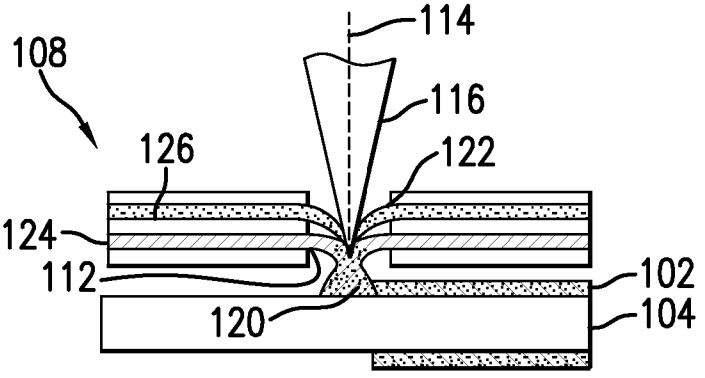

FIG. 1C

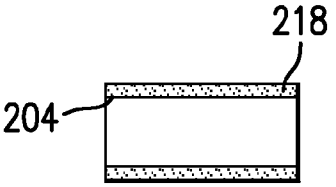

FIG.2A

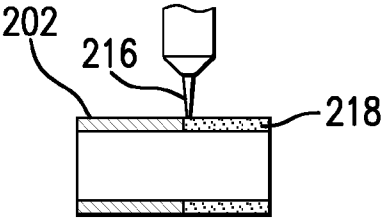

FIG.2B

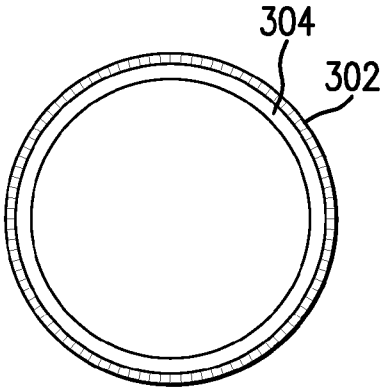

FIG.3A

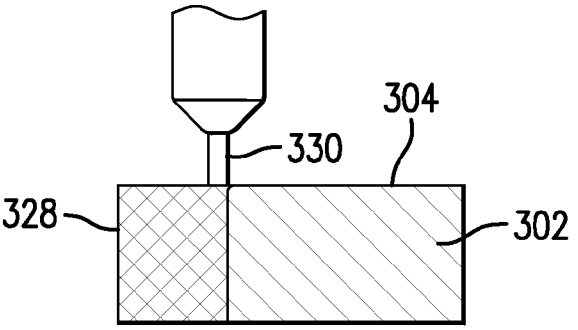

FIG.3B

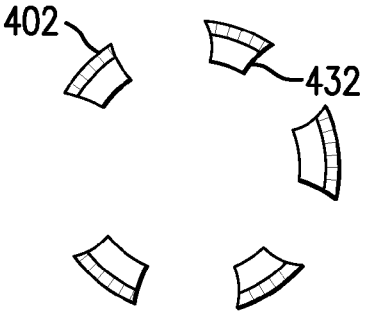

FIG.4A

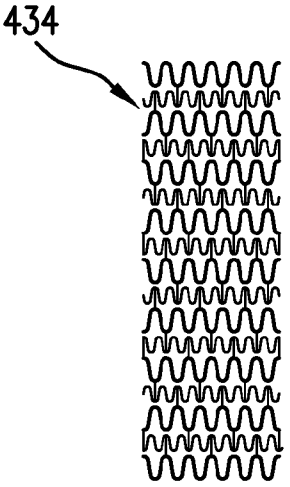

FIG.4B

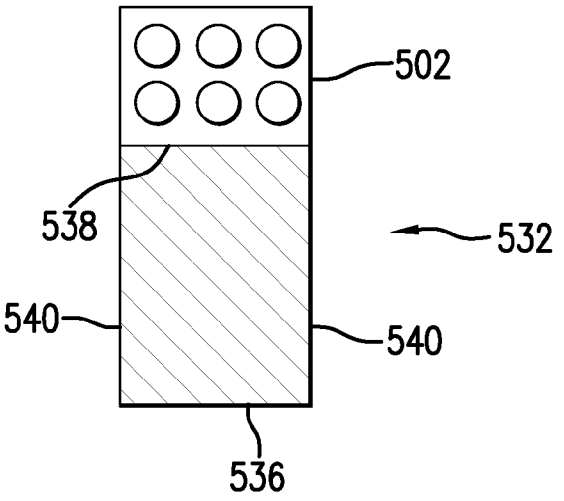

FIG.5A

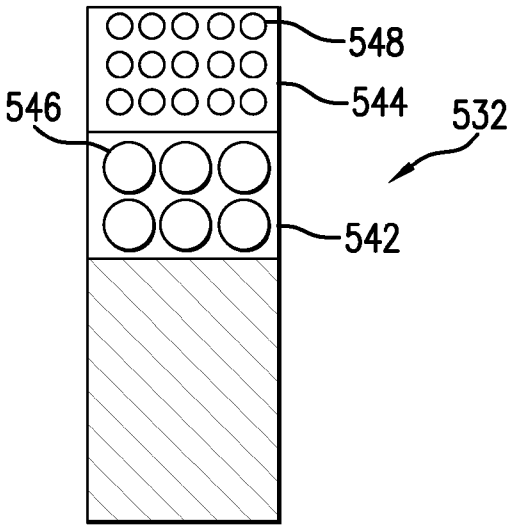

FIG.5B

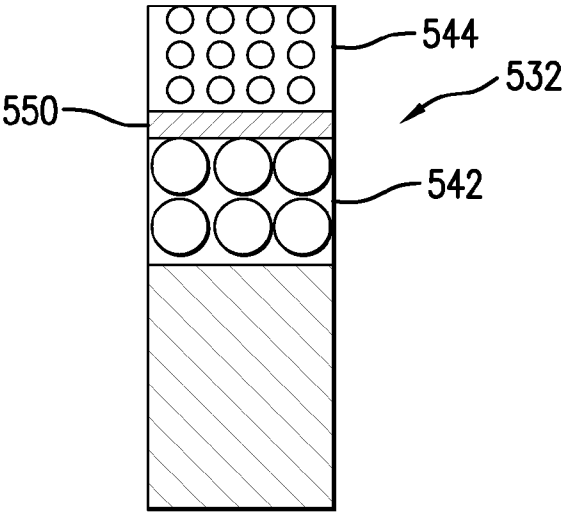

FIG.5C

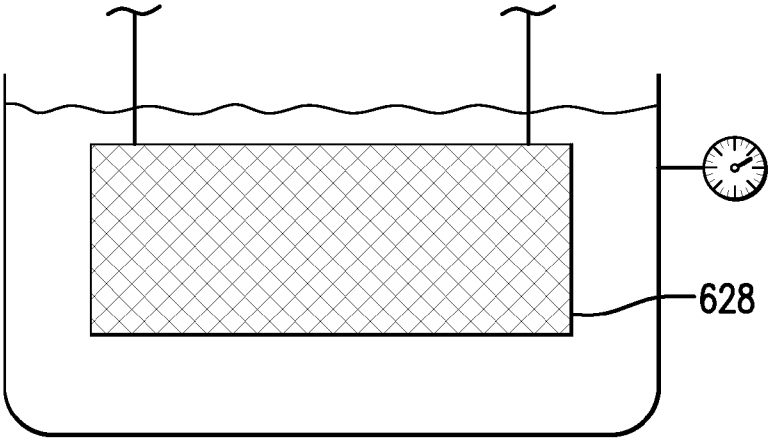

FIG.6A

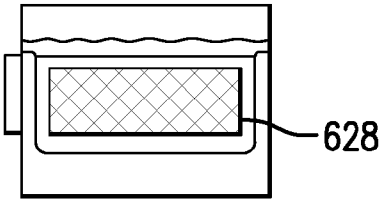

FIG.6B

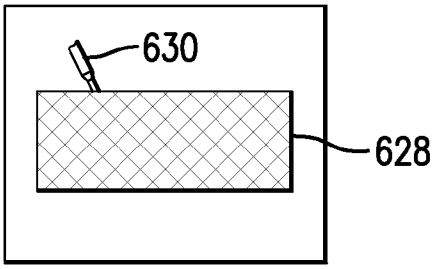

FIG.6C

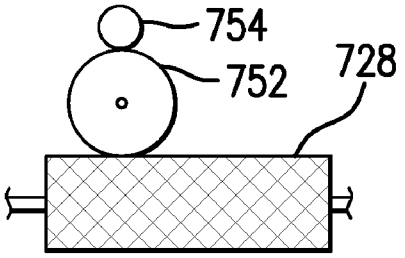

FIG.7A

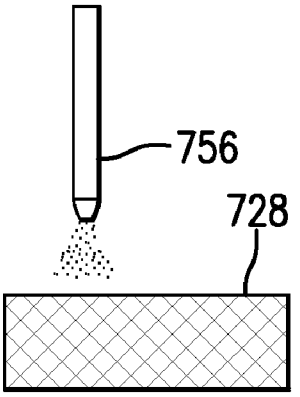

FIG.7B

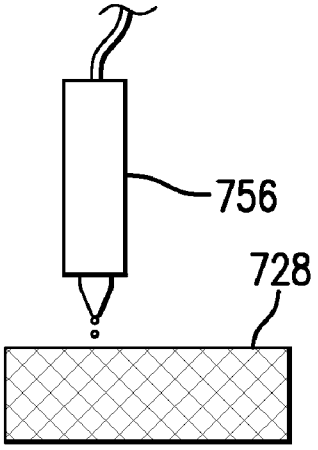

FIG.7C

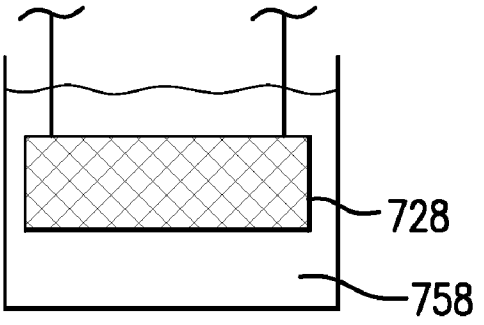

FIG.7D

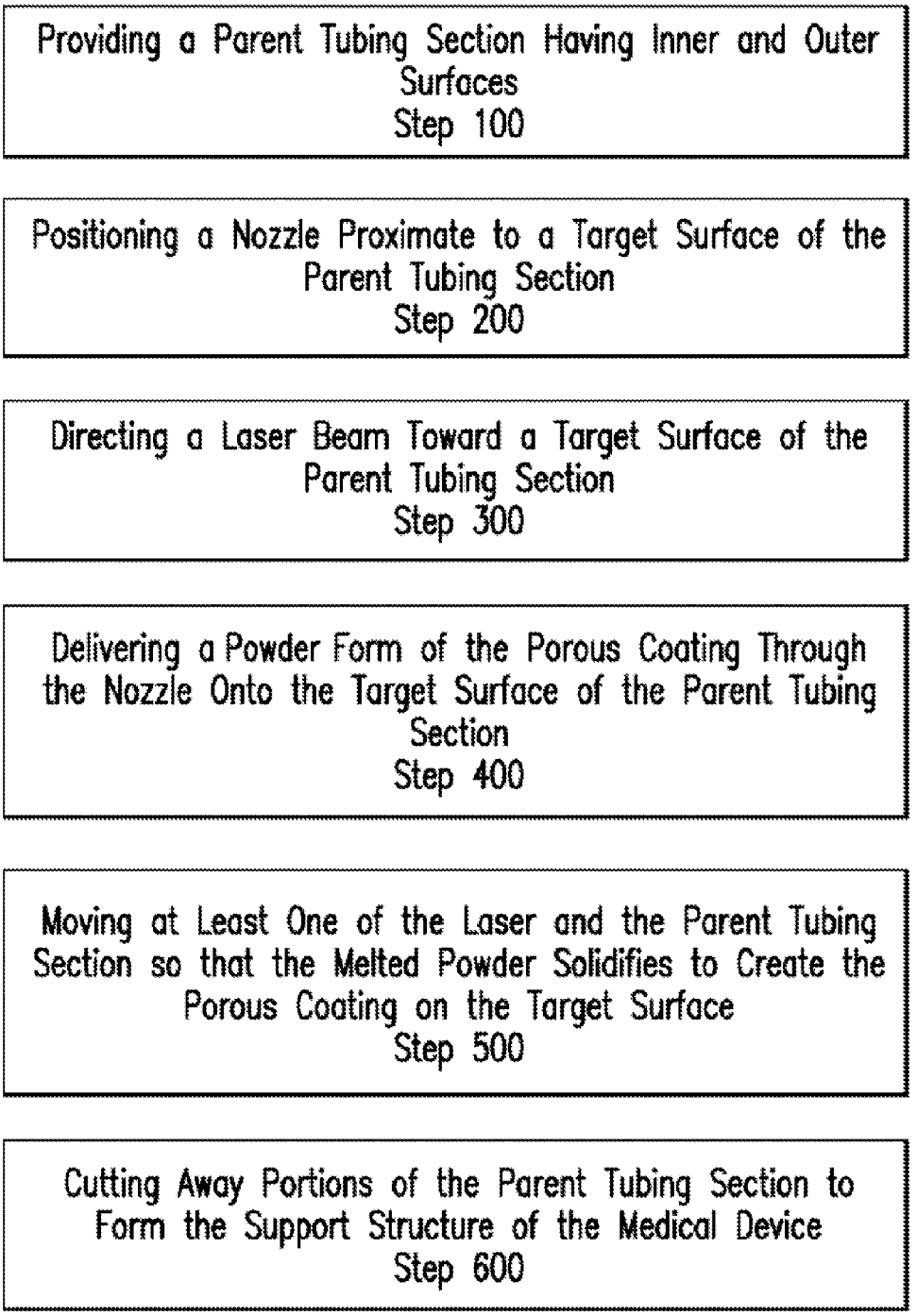
Providing a Parent Tubing Section Having Inner and Outer Surfaces
Step 100
Positioning a Nozzle Proximate to a Target Surface of the Parent Tubing Section
Step 200
Directing a Laser Beam Toward a Target Surface of the Parent Tubing Section
Step 300
Delivering a Powder Form of the Porous Coating Through the Nozzle Onto the Target Surface of the Parent Tubing Section
Step 400
Moving at Least One of the Laser and the Parent Tubing Section so that the Melted Powder Solidifies to Create the Porous Coating on the Target Surface
Step 500
Cutting Away Portions of the Parent Tubing Section to Form the Support Structure of the Medical Device
Step 600

FIG.8

MEDICAL DEVICE COATING BY LASER CLADDING

CROSS REFERENCE TO RELATED APPLICATION

The present application claims priority to U.S. provisional application Ser. No. 60/953,000 filed Jul. 31, 2007, the disclosure of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

The present invention generally relates to coated medical devices and methods and systems of making them.

BACKGROUND

The positioning and deployment of implantable medical devices at a target site is an often-repeated procedure of contemporary medicine. The devices, which can include implantable stents, cardiac rhythm management leads, neuromodulation devices, implants, grafts, defibrillators, filters, catheters and/or any implantable devices for systemic release of drugs, may be deployed for short and sustained periods of time, and may be used for many medicinal purposes, including the delivery of therapeutic agent and the reinforcement of recently re-enlarged lumens. When therapeutic agent is delivered by these devices it may be targeted for local application or more systemic delivery. For instance, therapeutic agent may be fed through and/or released from these devices.

Medical devices have been coated by dipping the device in a vat of therapeutic agent and by spraying therapeutic agent at the device. In each instance, polymers have been used to facilitate adherence between the therapeutic agent and the device.

Dipping and spraying systems can provide for inaccurate deposition of the therapeutic agent. When stents are coated in this fashion, for example, coating may remain between the struts of the stent. This "webbing" is unwanted, as it may reduce the accuracy of the dose delivered at the target site. Also, when polymers are used in these spraying and dipping processes, their use can inhibit the effectiveness of the therapeutic agent as both the polymer and the therapeutic agent may be easily deployed from the device rather than the therapeutic agent alone. Moreover, the polymer may create an inflammatory reaction.

BRIEF DESCRIPTION

The present invention is directed to improved medical device coating. The coating may be polymer-free, thereby eliminating any adverse effects of polymer coatings. In addition, or alternatively, the coating may be porous, facilitating the loading and release of therapeutic agent. The coating may be applied, if desired, on only the outer surface of the device, resulting in only abluminal delivery of therapeutic agent, which is desirable in certain applications.

The medical device coating may be made by the use of laser energy. The laser may be used to clad or otherwise adhere a coating to the device. The coating may be adhered to abluminal surfaces as well as to other surfaces of the device. Once coated, therapeutic agent may be loaded into the coating in order to be later released from the implant at or near a target site. The coating may be metallic, ceramic, bioceramic, or some other material. A plurality of coatings may be applied, for example in layers. The properties and position of the coatings may be controlled by the composition of the coating, the type and amount of laser energy employed during the cladding and the environment in which the method is carried out.

When a stent is manufactured in accordance with an embodiment of the invention, the method employed may comprise providing a workpiece having inner and outer surfaces and positioning a nozzle adjacent the outer surface of the workpiece. A coating material may then be directed through the nozzle towards a surface of the workpiece. A laser beam may be directed at the coating material (and perhaps the workpiece) to form a melt pool on the surface of the workpiece. This melt pool of coating material (and perhaps material from the workpiece) can cool and harden, creating a porous layer of the coating material secured to the surface of the workpiece. Portions of the workpiece, which may be in the shape of a tube, may be cut away to form a coated stent structure. This coated stent structure may then be loaded with therapeutic agent.

In some embodiments, the porous coatings may be selectively applied in specified areas along the length of the workpiece or stent material, and a number of porous coatings may be applied. The coating may be applied such that it controls or otherwise sustains the elution rate of therapeutic agent carried by the coating.

The invention may be embodied by numerous methods, systems, devices, and products, and the description and drawings provided herein are examples of the invention. Other embodiments, which incorporate some or all of the steps and features, are also possible.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring to the drawings, which form a part of this disclosure:

FIG. **1***a* shows a system for applying porous coatings to a tubing section as may be employed in accordance with embodiments of the present invention;

FIG. **1***b* shows an enlarged cross-sectional view of a nozzle that may be employed with the system of FIG. **1***a* in accordance with embodiments of the present invention;

FIG. **1***c* shows an enlarged cross-sectional view of another nozzle that may be employed with the system of FIG. **1***a* in accordance with embodiments of the present invention;

FIGS. **2***a-b* show a tubing section and powdered coating before and during the application of laser energy as may be employed with embodiments of the present invention;

FIG. **3***a* shows an end view of a tubing section and porous coating as may be employed in accordance with embodiments of the present invention;

FIG. **3***b* shows a laser cutting portions of a tube with a porous coating as may be employed in accordance with embodiments of the present invention;

FIG. **4***a* shows a cross-sectional view of stent struts while FIG. **4***b* shows a plan view of a stent, each coated in accordance with embodiments of the present invention;

FIG. **5***a-c* show cross-sectional views of stent struts having porous coatings as may be applied in accordance with embodiments of the present invention;

FIGS. **6***a-c* show systems for polishing, sintering, and cleaning a medical device as may be employed in accordance with embodiments of the present invention;

FIGS. **7***a-d* show drug loading systems that may be employed in accordance with embodiments of the present invention; and

FIG. **8** is a flow chart of methods that may be employed in accordance with embodiments of the present invention.

DETAILED DESCRIPTION

Conventional laser cladding processes have been used for hard-facing (e.g., applying a layer of harder material (e.g., tungsten carbide) onto a softer base layer of material (e.g., stainless steel)). These conventional processes contemplate the use of one or more homogenous hard-faced layer(s), where pores and cracks in the hard-faced layer are undesirable. Laser cladding processes have been utilized for hard-facing new components during production and restoring worn-down surfaces of existing components.

For example, as discussed in M. F. Schneider, "Laser Cladding" (Ph. D. Thesis, University of Twente, Enschede, The Netherlands, 1998), pages 1-181, laser cladding processes have been used in industrial applications to hard-face and refurbish gas turbine blades and diesel engine exhaust valves. In addition, as discussed in U.S. Pat. No. 6,122,564 to Koch, which issued on Sep. 19, 2000, laser cladding has also been proposed for use in general industrial processes for improving surface quality and creating components by building up layers, such as in conventional rapid prototyping processes.

In contrast to conventional laser cladding processes, in which pores in the hard-faced layer(s) were undesirable, embodiments of the present invention relate to the creation of "porous" coatings on the surface of substrates, such as, for example, stents. These porous coatings can be used to control drug elution rates.

Embodiments of the present invention include at least the following advantages over existing porous coating processes: porous coatings may be created for various materials (e.g., metals and ceramics); laser energy can be accurately directed and controlled to melt or partially melt the coating material and the surface layer of the substrate to provide sound adhesion of the porous layer; heat affected zones can be kept to a minimum; the particle size(s) of the powder can be chosen so as to regulate the pore size and pore density of the resulting layer in conjunction with laser energy level and particle velocity; different particle sizes and laser energy can be used for adjacent layers to provide varying porosity between layers; and different material types can be applied simultaneously or discrete layers of different material can be built up.

As discussed above, the present invention generally relates to methods for making medical devices with porous coatings. The medical devices may comprise metallic, ceramic, bioceramic, and other types of materials. The coatings may be applied to the medical devices with the application of laser energy. The coatings may also be portions of the medical device that have been treated by the laser itself without the use of additional coating material. When a coating material is used, the coating material may melt upon being exposed to the laser, by virtue of heat supplied by the laser, and may solidify as it cools. The laser may also be pulsed to minimize transfer of heat to the device being coated. This melting process may not only serve to affect the final porosity of the coating but it may also serve to adhere the coating material to the medical device. The porosity of the coating may be used to contain and regulate the release of therapeutic agent from the medical device. In some instances, the coating is polymer-free and, thus, may eliminate any potentially inflammatory reactions associated with the use of polymers on medical devices. In other instances, non-porous coatings may be selectively applied using methods described herein. For example, non-porous radiopaque coatings (e.g., platinum, gold, tantilum, iridium, etc.) may be applied to the device.

The porous coatings may be loaded with therapeutic agents by various methods including injecting, spraying, rolling, dipping, hydraulic pressure, vacuum impregnation, vacuum spraying or otherwise forcing therapeutic agent into one or more voids or spaces of the porous coatings of the medical device.

FIG. **1***a* illustrates a system **100** for applying a porous coating **102** to a workpiece, which in this embodiment is a tubing section **104** that may be used to form a medical device. As seen FIG. **1***a*, the workpiece to be coated may be positioned on a mandrel **106** that is itself near a nozzle **108**. The nozzle **108** may contain a passageway for coating material and may also contain an opening to allow a laser beam to reach workpiece **104**. The nozzle **108** and mandrel **106** may each move such that coating **102** ejected from the nozzle **108** may coat the entire outer section of the workpiece **104**. For instance, the mandrel **106** may rotate while the nozzle **108** may move linearly above its surface. Likewise, the nozzle may rotate in a circle while the mandrel may move linearly.

FIG. **1***b* shows an enlarged cross-sectional view of the nozzle **108** of FIG. **1***a*. In FIG. **1***b* it can be seen that the nozzle **108** may have two coaxially disposed openings **110**, **112**. Both openings may be arranged about a central axis **114** of the nozzle **108** and the first opening **110** can be configured such that a laser beam **116** can travel therethrough. A positive gas flow can be maintained on the first orifice to prevent splash back onto a component (e.g., lens and/or optics) of the laser. Also as seen in FIG. **1***b*, the second opening **112** may be concentrically arranged around the first opening **110**. The second opening **112** may be in communication with both shield gas and porous coating powder sources (not shown). Both the shield gas and a porous coating powder may be dispensed through this second opening **112** during a coating process.

Once the powder is dispensed or delivered towards a target surface of the device such as by using the shield gas, the powder may intersect the laser beam **116** and be melted and deposited on the tube. As the liquid hardens, a porous coating is formed. The porosity of the coating may be controlled by controlling the flow of the shield gas, which can affect both the deposition rate of the powder and the amount of gas entrained in the melted powder. Also, the particle size of the powder may be selected to obtain a desired porosity.

Various lasers may be used in the embodiments of the present invention. For example, carbon dioxide lasers producing infrared beams of light having principal wavelengths between about 9 and 11 micrometers may be suitable. Another suitable laser may be the Nd:YAG laser, which has a wavelength of about 1.06 micrometers.

In conventional laser cladding processes, a carbon dioxide laser is typically used with a 5 kW power rating or greater. In contrast, in certain embodiments of the present invention, which may be used for cladding lattice structures (e.g., with widths and thicknesses on the order of 0.5 mm or less) of medical devices such as stents, lower powered lasers can be used to avoid damaging the target material. For example, a 50 W to 1 kW YAG pulsed or carbon dioxide laser with a wavelength of about 1.06 micrometers may be used.

The laser beams used with embodiments of the present invention may be pulsated on and off in a cyclic or non-cyclic fashion. Laser pulsation may minimize the amount of heat transferred to the workpiece during the coating process. This can be done to minimize damage to the workpiece. In addition, operating parameters of the laser may be varied to change the properties of the porous coating. For example, the focus of the laser and/or the power of the laser may be changed to achieve desired porosities.

The shield gas may be inert and/or non-inert gases. For example, argon, helium, and/or nitrogen may each be suitable in certain embodiments of the present invention. The shield gas may be used to deliver the powder and can be used to shield the heated device, such as a metallic stent, from the reactive gases in air which can cause undesirable reactions in the metal. Also, the workpieces such as tubing section **104** may be comprised of bio-stable metallic, ceramic, bio-ceramic, and/or polymeric materials. For example, a metallic tube of stainless steel, CoCr, NiTi, or platinum enriched stainless steel may be used.

The powder **118** which forms the porous coatings **102** may be comprised of metallic materials including, but not limited to stainless steel, titanium, CoCr, platinum enriched stainless steel, NiTi, and combinations thereof. Ceramic coatings, including bio-ceramic coatings, may also be used. For example, bio-ceramic coatings such as calcium phosphate (hydroxyapatite) can be applied to metallic substrates using the coating processes described herein. The bio-ceramic coatings may be used on a surface of the medical device for controlled drug delivery and/or to promote endothelial regrowth. Since a bio-ceramic such as calcium phosphate can be found naturally in the body, the bio-compatible properties of the coatings may facilitate endothelialization of a medical device coated in this fashion.

As suggested, the properties and delivery of the powder **118** may be varied. For example, the amount of powder used, the types of powder, and/or the velocity at which the powder exits the second opening of the nozzle **108** may all be changed to achieve different porosities and/or pore sizes of the porous coating **102**. In use, the powder **118** may be interfaced with the shield gas and directed out of the second opening **112** in a direction towards and/or at the laser beam **116**. The powder **118** may contact the laser beam **116** and the laser beam **116** can melt the powder **118**. Consequently, the laser beam **116** may cause the powder **118** to melt and can form a melt pool **120** on the target surface of the parent tubing section. Then, either the laser beam, the parent tubing section, and/or both the laser beam/parent tubing section may be moved away from the other and the melt pool may solidify. Thus, a porous coating can be formed on the target surface of the parent tubing section.

The movements of the nozzle **108**, laser **116** and/or tubing section **104** may be operated by a control system. The control system may be programmable with instructions or other retained data which may be unique to each parent tubing section to be coated and may account for the unique external pattern and precise dimensions of the final medical device. The controller system may also hold unique instruction sets for many different tubing sections and/or medical devices. The control system may also control, store, and/or process operating parameters of the mandrel and/or laser such as laser power, laser focal point, rotation speed, velocity of the powder stream, etc. Sensors may also be used for monitoring the thickness of the coating, the physical properties of the porous coating (e.g., the rate of solidification and temperature of the melt pool), and the temperature of the parent tubing section.

As seen in FIG. **1***c*, other nozzle arrangements are also possible. As shown in FIG. **1***c*, two or more openings **112**, **122** may be used for delivering the same or different shield gases and powders. Alternatively, the second opening **112** of FIG. **1***b* may itself be in communication with multiple shield gas and powder sources. Similarly, with respect to FIG. **1***b*, although only a first opening **110** for the laser **116** is shown in FIG. **1***b*, multiple lasers beams may extend through the first opening or through multiple openings.

In FIG. **1***c*, two different powders **124**, **126** are being delivered. In this example, the first powder **124** may be delivered from the second opening **112** while the second powder **126** may be delivered from a third opening **122**; however, other arrangements are possible. It can also be seen that, in this example, the second and third openings **112**, **122** can extend in a direction perpendicular to the central axis **114** of the nozzle. In this figure, the first powder **124** melts when contacted by the laser **116**; however, the second powder **126** does not melt. Therefore, the second powder **126** becomes encapsulated within the porous coating **102** formed by the first powder **124**. Such an arrangement may be used to enhance porosity and/or enhance surface properties such as roughness and hydrophilicity of the porous coating **102**. These surface properties may be useful for promoting endothelial cell adhesion.

In addition, the second powder **126** may be dissolvable within a solvent such as an acid. The acid can be selectively applied to the porous coating **102** over the length of the medical device. The acid in turn can dissolve the second powder **126** in certain areas, thus varying the porosity in these regions. Still other arrangements are possible.

As seen in FIGS. **2***a-b*, the powder **218** may also be applied in a separate step if desired. For example, the powder **218** may be applied to the tubing section **204**, such as in a paste, in a manner similar to affixation methods that may be used in soldering processes. A laser **216**, as shown in FIG. **2***b*, may then be used to melt the powder **218**, a melt pool forms and is then allowed to solidify to form a porous coating **202**.

FIG. **3**A shows an end view of a tubing section **304** having a porous coating **302** applied to an outer surface. After the porous coating **302** is applied, the tubing section **304** may be cut to form the medical device **328**. FIG. **3***b* shows a laser **330** cutting material away from a tubing section **304**. For example, after the tubing section **304** has been coated with a porous coating **302** or series of porous coatings, the laser **330** may be used to cut away waste metal, thus leaving the desired geometry of the medical device **328** intact.

For example, FIG. **4***a* shows a cross-sectional view of a plurality of stent struts **432** which have a porous coating **402** and which were cut from a tubing section in accordance with an embodiment of the present invention.

FIG. **4***b* shows a side view of a stent **434** as may be coated and cut in accord with a method of the present invention. A porous coating or coatings may applied to portions of or along the entire length of the stent **434**. The struts shown in FIG. **4***a* are struts **432** that may comprise and make up this stent **434**.

The stent **434** of FIG. **4***b* as well as in the other illustrations may be self-expanding, mechanically expandable, or a hybrid stent which may have both self-expanding and mechanically expandable characteristics. The stent may be made in a wide variety of designs and configurations, and may be made from a variety of materials including plastics and metals.

While the device shown in this figure is an implantable stent, many other medical devices and implants may be coated in accord with the methods of the present invention. For example, other medical devices that may be coated include cardiac rhythm management leads, neuromodulation devices, implants, grafts, defibrillators, filters, catheters and/or any implantable devices for systemic release of drugs may be used.

FIG. **5***a* is a side sectional view of a stent strut **532** as may be coated in accordance with embodiments of the present invention. The stent strut **532** shown in FIG. **5***a* has an inner surface **536**, an outer surface **538**, two cut faces **540**, and a porous coating **502**. As can be seen, the porous coating **502** may cover only one surface of the strut **532**. In this example,

since the porous coating **502** is on the outer (or abluminal) surface **538** only, therapeutic agent loaded within the porous coating can be limited to abluminal delivery. Other arrangements are possible. For example, in other examples, bioceramic coatings on other surfaces may be used in conjunction with the outer porous coating, such as on the cut faces, to promote endothelial re-growth.

FIG. **5***b* shows another example of how coatings may be applied in accord with the invention. In FIG. **5***b*, a first coating **542** and a second coating **544** have been applied to a stent strut **532**. As can be seen, the first coating **542** is in contact with the outer surface **538** of the strut **532** while the second coating **544** is in contact with the first coating **542** and further covers the outer surface **538** of the strut **532**. This second coating **544** may be applied in accord with the embodiments of the present invention. It may also be applied with different methods and processes. In this example, as well as with the others described herein, if a second coating is employed this coating may comprise the same materials as the first coating and it may differ from the materials used for the first coating. In still other examples, the coating may be applied in other patterns as well. For example, it may be applied to the inner surface and not the outer surface, likewise it may be applied to both the inner and outer surfaces if desired. In an exemplary embodiment, the outer surface is coated and the two cut faces as well as the inner surface are not.

Also as shown in this figure, the porosity and/or pore size of each coating applied may differ. For instance, layers of different porosity can be applied over each other. As seen in FIG. **5***b*, the first coating **542** may have larger pores **546** to act as a drug reservoir, while the second coating **544** has smaller pores **548** that can be applied over the first coating **542** to regulate the drug release.

As discussed, embodiments of the present invention may include porous coatings that comprise voids and interstices of various sizes, and may have dimensions in a nanometer scale and a micrometer scale. These voids and interstices may be homogenous in size and non-homogeneous in size. Each coating may also be comprised of two or more porous regions with different porosities and pore sizes. The same or different therapeutics may also be loaded into each individual region. Since the rate of drug elution from a porous region may be determined by the pore size of the coating, it may be preferred that the pores are relatively small, for example, in the micrometer or nanometer scale. Smaller size pores may be preferred as they can enable sustained therapeutic delivery over a reasonable timescale, for example, about three months. In order to provide enough therapeutic agent to have a therapeutic effect, it may be preferred that all available spaces in the porous regions are loaded with therapeutic agent.

FIG. **5***c* shows still another example of how a coating can be applied in accord with the invention. As can be seen, the first coating is in contact with the outer surface of the stent strut while a non-porous radiopaque layer **550** is located in between the first coating **542** and a second coating **544**. The radiopaque layer **550** may be applied to make the final medical device more visible under fluoroscopy to facilitate placement of the device within a patient. The methods that embody the invention may be used to selectively apply non-porous radiopaque layers or stripes of material such as, for example, tantilum, platinum, gold, iridium, and platinum iridium.

In accordance with embodiments of the present invention, after the medical device is laser cut (FIG. **3***b*), the medical device may be polished and cleaned. For example, as shown in FIG. **6***a*, the medical device **628** may be polished to remove burrs from a surface of the device.

In the example of FIG. **6***a*, the medical device **628** is being electropolished in a temperature controlled bath of electrolyte; however, other polishing techniques are possible.

Likewise, as shown in FIG. **6***b*, the medical device **628** may be cleaned, such as by ultrasound with an acid (e.g., nitric acid) and/or solvent (e.g., alcohol, toluene, THF, etc.) prior to being loaded with coating.

As seen in FIG. **6***c*, during the coating processes described herein, the medical device **628** may also be selectively sintered with a laser **630**. For example, selective laser sintering may be used to apply various surface features and/or textures to the medical device **628**. In addition, the medical device **628** may be selectively sintered to change the porosity of select regions of the porous coating along the length of the stent.

After the medical device is cut, polished, cleaned, and/or sintered, the porous coating may receive coating, including coatings having therapeutic agent. The porous coating or series of porous coatings may be loaded with therapeutic agent by injecting, spraying, rolling, dipping, hydraulic pressure, vacuum impregnation, vacuum spraying or otherwise forcing therapeutic agent into one or more voids or spaces of the porous coating or coatings of the medical device. For example, the medical device **728** may be roll coated with a roller **752** and metering device **754** as shown in FIG. **7***a*. The medical device may be spray coated and/or injected with therapeutic agent via nozzles **756** as shown in FIGS. **7***b* and **7***c*, respectively. Still further, the porous coating may be immersed in a solution **758** containing therapeutic agent. Other loading methods are also possible.

FIG. **8** shows a flow chart including method steps that may be employed with embodiments of the present invention for making a medical device having a porous coating. In the example of FIG. **8**, step **100** may include providing a parent tubing section having inner and outer surfaces. Step **200** may include positioning a nozzle proximate to a target surface of the parent tubing section. Step **300** can include directing a laser beam towards a target surface of the parent tubing section. Step **400** may include delivering a powder form of the porous coating through the nozzle onto the target surface of the parent tubing section. Step **500** may include moving at least one of the laser and the parent tubing section so that melted powder solidifies to form the porous coating on the target surface of the parent tubing section. Step **600** may include cutting away portions of the parent tubing section to form the support structure of the medical device.

In other embodiments the sequence of steps may be reordered and steps may be added or removed. The steps may also be modified.

While various embodiments have been described, other embodiments are plausible. It should be understood that the foregoing descriptions of various examples of the medical device and porous coatings are not intended to be limiting, and any number of modifications, combinations, and alternatives of the examples may be employed to facilitate the effectiveness of delivering therapeutic agent from the porous coating.

A suitable list of drugs and/or polymer combinations is listed below. The term "therapeutic agent" as used herein includes one or more "therapeutic agents" or "drugs." The terms "therapeutic agents" or "drugs" can be used interchangeably herein and include pharmaceutically active compounds, nucleic acids with and without carrier vectors such as lipids, compacting agents (such as histones), viruses (such as adenovirus, adenoassociated virus, retrovirus, lentivirus and α-virus), polymers, hyaluronic acid, proteins, cells and the like, with or without targeting sequences.

Specific examples of therapeutic agents used in conjunction with the present invention include, for example, pharmaceutically active compounds, proteins, cells, oligonucleotides, ribozymes, anti-sense oligonucleotides, DNA compacting agents, gene/vector systems (i.e., any vehicle that allows for the uptake and expression of nucleic acids), nucleic acids (including, for example, recombinant nucleic acids; naked DNA, cDNA, RNA; genomic DNA, cDNA or RNA in a non-infectious vector or in a viral vector and which further may have attached peptide targeting sequences; antisense nucleic acid (RNA or DNA); and DNA chimeras which include gene sequences and encoding for ferry proteins such as membrane translocating sequences ("MTS") and herpes simplex virus-1 ("VP22")), and viral liposomes and cationic and anionic polymers and neutral polymers that are selected from a number of types depending on the desired application. Non-limiting examples of virus vectors or vectors derived from viral sources include adenoviral vectors, herpes simplex vectors, papilloma vectors, adeno-associated vectors, retroviral vectors, and the like. Non-limiting examples of biologically active solutes include anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); antioxidants such as probucol and retinoic acid; angiogenic and anti-angiogenic agents and factors; anti-proliferative agents such as enoxaparin, everolimus, zotarolimus, angiopeptin, rapamycin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, acetyl salicylic acid, and mesalamine; calcium entry blockers such as verapamil, diltiazem and nifedipine; antineoplastic/antiproliferative/anti-mitotic agents such as paclitaxel, 5-fluorouracil, methotrexate, doxorubicin, daunorubicin, cyclosporine, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; antimicrobials such as triclosan, cephalosporins, aminoglycosides, and nitrofurantoin; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; nitric oxide (NO) donors such as linsidomine, molsidomine, L-arginine, NO-protein adducts, NO-carbohydrate adducts, polymeric or oligomeric NO adducts; anti-coagulants such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, enoxaparin, hirudin, Warfarin sodium, Dicumarol, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet factors; vascular cell growth promoters such as growth factors, growth factor receptor antagonists, transcriptional activators, and translational promoters; vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; agents which interfere with endogenous vascoactive mechanisms; survival genes which protect against cell death, such as anti-apoptotic Bcl-2 family factors and Akt kinase; and combinations thereof. Cells can be of human origin (autologous or allogenic) or from an animal source (xenogeneic), genetically engineered if desired to deliver proteins of interest at the insertion site. Any modifications are routinely made by one skilled in the art.

Polynucleotide sequences useful in practice of the invention include DNA or RNA sequences having a therapeutic effect after being taken up by a cell. Examples of therapeutic polynucleotides include anti-sense DNA and RNA; DNA coding for an anti-sense RNA; or DNA coding for tRNA or rRNA to replace defective or deficient endogenous molecules. The polynucleotides can also code for therapeutic proteins or polypeptides. A polypeptide is understood to be any translation product of a polynucleotide regardless of size, and whether glycosylated or not. Therapeutic proteins and polypeptides include as a primary example, those proteins or polypeptides that can compensate for defective or deficient species in an animal, or those that act through toxic effects to limit or remove harmful cells from the body. In addition, the polypeptides or proteins that can be injected, or whose DNA can be incorporated, include without limitation, angiogenic factors and other molecules competent to induce angiogenesis, including acidic and basic fibroblast growth factors, vascular endothelial growth factor, hif-1, epidermal growth factor, transforming growth factor α and β, platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α, hepatocyte growth factor and insulin like growth factor; growth factors; cell cycle inhibitors including CDK inhibitors; anti-restenosis agents, including p15, p16, p18, p19, p21, p27, p53, p57, Rb, nFkB and E2F decoys, thymidine kinase ("TK") and combinations thereof and other agents useful for interfering with cell proliferation, including agents for treating malignancies; and combinations thereof. Still other useful factors, which can be provided as polypeptides or as DNA encoding these polypeptides, include monocyte chemoattractant protein ("MCP-1"), and the family of bone morphogenic proteins ("BMPs"). The known proteins include BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Currently preferred BMPs are any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7. These dimeric proteins can be provided as homodimers, heterodimers, or combinations thereof, alone or together with other molecules. Alternatively or, in addition, molecules capable of inducing an upstream or downstream effect of a BMP can be provided. Such molecules include any of the "hedgehog" proteins, or the DNAs encoding them.

The examples described herein are merely illustrative, as numerous other embodiments may be implemented without departing from the spirit and scope of the exemplary embodiments of the present invention. Moreover, while certain features of the invention may be shown on only certain embodiments or configurations, these features may be exchanged, added, and removed from and between the various embodiments or configurations while remaining within the scope of the invention. Likewise, methods described and disclosed may also be performed in various sequences, with some or all of the disclosed steps being performed in a different order than described while still remaining within the spirit and scope of the present invention.

What is claimed is:

1. A method of making a medical device with a porous coating, the method comprising:

providing a workpiece sized to fit within lumens of the body, the workpiece having an accessible surface;

positioning a nozzle adjacent the accessible surface;

ejecting a coating material from the nozzle toward the accessible surface;

directing a laser beam toward the coating material ejected from the nozzle, thereby melting the coating material ejected from the nozzle with the laser;

allowing the melted coating material to cool and form a porous coating on the workpiece; and

loading the porous coating with a therapeutic agent.

2. The method of claim **1** wherein the coating material is a powder.

3. The method of claim **1** wherein the coating material is a paste.

4. The method of claim **1** further comprising directing a shield gas toward the workpiece.

5. The method of claim **1** wherein the workpiece is a tube and wherein after the porous coating is formed, the tube is cut to form a stent.

6. The method of claim **1** wherein the workpiece is a stent.

7. The method of claim **1** further comprising:

ejecting a second coating material from the nozzle;

melting the second coating material with the laser; and

allowing the melted second coating material to cool and form a second porous coating on the workpiece, wherein the porosity of the second porous coating is different than the porosity of the first porous coating.

8. The method of claim **1** further comprising polishing the medical device.

9. The method of claim **1** wherein a portion of the workpiece is melted when the coating material is melted by the laser.

10. The method of claim **1** wherein the laser is pulsed on and off.

11. The method of claim **1** wherein the laser is a CO_2 laser.

12. The method of claim **1** further comprising applying a non-porous radiopaque layer to the porous coating.

13. The method of claim **1** wherein the coating material is metallic.

14. The method of claim **1** wherein the coating material is ceramic.

15. The method of claim **1** wherein the coating material is bio-ceramic.

16. The method of claim **1** wherein the coating material comprises calcium phosphate.

17. The method of claim **1**, wherein the laser is directed through the nozzle towards the coating material ejected from the nozzle.

18. A method for making an implantable medical device having a porous coating, the method comprising:

providing a tube having inner and outer surfaces;

applying a powder ejected from a nozzle onto an outer surface of the tube;

directing a laser beam toward the powder to melt the powder ejected from the nozzle such that melted powder is formed along the outer surface of the tube;

allowing the melted powder to cool and solidify to form a porous coating on the outer surface of the tube; and

cutting away portions of the tube to form an implantable medical device.

19. The method of claim **18** further comprising loading the porous coating with a therapeutic agent.

20. The method of claim **18** further comprising directing a shield gas toward the outer surface of the tube.

21. The method of claim **20** wherein the portions of the tube are cut away to form the implantable medical device prior to applying the powder to the outer surface of the tube.

22. The method of claim **1**, further comprising ejecting a second coating material from the nozzle, the second coating material not being melted by the laser and being encapsulated with the porous coating formed by the melted coating material.

23. The method of claim **22**, wherein the second coating material and the coating material are ejected from different nozzle openings.

24. The method of claim **18**, wherein the laser is directed through the nozzle towards the powder ejected from the nozzle.

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